Remarks

This application seeks protection for certain novel compounds that are inhibitors of the serine protease, Factor Xa, and are useful for the treatment of thrombotic disorders. It is a continuation of the national stage of an international application, the claims of which were drafted in accordance with international practice. The claims in the parent application have been limited to one specific compound.

Applicants now wish to amend the application to bring it into conformity with United States patent practice. It is believed that these amendments will place the application in order for allowance.

Claims 13 to 18, 20, 25, 28, 29, 31 and 32 have been cancelled, without prejudice.

Claims 4 to 6, 9 to 12, 19, 21 to 24, 27 and 33 have been rewritten to remove improper claim dependencies.

Claim 1 has been amended by incorporating definitions from the specification for:-

R_2: page 23, line 20 to page 25, line 7;

R_1: page 25, line 33 to page 26, line 15;

R_{1j}: page 26, lines 16 to 30;

-X-X-: page 9, lines 27-28 and Claim 13;

Y: page 9, line 34 and Claim 14;

Cy: page 15, lines 16 to 24 and Claim 15; and

R_{3a}: page 16, line 6 to page 17, line 16 and Claim 18.

Claim 2 has been amended to remove definitions also found in Claim 1. Claim 2 has been further amended by inserting the value "piperidin-4-yl (which may bear a 1-methyl substituent,)" in the definition of CHR_eR_f before "or indan-2-yl". Basis for this amendment may be found in the corresponding passage at page 8, lines 22 to 23 of the specification. It has further been amended by incorporating the subject matter of Claims 16 and 20.

Claim 7 has been amended by inserting a definition for L, based upon page 11, line 16.

Claim 9 now incorporates the definition for R_2 at page 26, line 31 to page 28, line 10 of the specification.

Claim 10 now incorporates the definition for R_2 at page 28, line 11 to page 29, line 29 of the specification.

In Claim 21, minor grammatical corrections have been made.

Claim 26 has been amended to exclude the compound 1-(indole-6-carbonyl-D-phenylglycinyl)-4-(1-methylpiperidin-4-yl)piperazine, which is claimed specifically in the parent application.

Claim 30 has been amended in a manner consistent with the amendment made in the method claim in the parent application. Support may be found at page 2, lines 21 to 26 of the specification.

Claim 33 has been amended to introduce a definition for Cy, by referring back to Claims 1, 21 and 22.

New Claim 34 is based upon Claim 25.

New Claim 35 is based upon Claim 27.

New Claim 36 is based upon Claim 30.

New Claim 37 is also based upon Claim 30, but is limited to a method of treating a human body.

INFORMATION DISCLOSURE STATEMENT

As a means of complying with the duty of disclosure, Applicant's submit an "Information Disclosure Statement by Applicant" on PTO Form PTO/SB/08A for consideration by the Examiner. Since this statement is being submitted during the period specified in 37 C.F.R. § 1.97(b), no fee is due for this submission.

In accordance with 37 C.F.R. 1.98(d), it is believed that a copy of each cited reference may be found at in the file of the parent application. If this is incorrect, the Examiner is kindly requested to contact the undersigned to request copies.

Applicants would also like to provide the Examiner the following background information:

BACKGROUND INFORMATION

This application claims compounds first disclosed in PCT/GB00/02302, from which the parent of the present application claims priority under 35 U.S.C. § 119.

PCT/GB00/02302 has entered the U.S. national stage as U.S. patent application serial number 09/926,712. The claims in the 09/926,712 application have been amended so as not to read on any of the compounds originally claimed in the present application.

The compounds were invented in the course of a research collaboration between Eli Lilly and Company (the assignee of record) and Protherics Molecular Design Limited (now Tularik Limited, a subsidiary of Tularik Inc). The

predecessor company of Protherics Molecular Design Limited was Proteus Molecular Design Limited.

This application forms part of a portfolio of patent applications directed to serine protease inhibitors, some of which belong to Eli Lilly and Company, and some of which belong to Tularik Limited. The history of this portfolio traces back to a research project on serine protease inhibitors started by Proteus Molecular Design Limited. The undersigned is responsible for handling the applications in this portfolio.

A listing of the co-pending applications and patents in the portfolio is provided on the next page.

Co-Pending Lilly and Tularik Applications and Patents

Co-pending applications - Assigned to Eli Lilly and Company

09/926,712 (national stage of WO 00/76971)
09/926,716 (national stage of WO 00/76970 - abandoned)
10/030,188 (national stage of WO 01/96303)
10/030,186 (national stage of WO 01/96304)
10/030,189 (national stage of WO 01/96296)
10/477,192 (national stage of WO 02/100847)

Co-pending applications and patents - Assigned to Tularik Limited

US 6262069 and **US 6420438** (national stage of WO 99/11657 and continuation)
09/988,082 (continuation-in-part of 09/485,678, WO 99/11658 and of WO 00/77027)
10/148,174 (national stage of WO 01/44226)
10/296,245 (national stage of WO 01/96305)
10/432,365 (national stage of WO 02/47762)

COMMUNICATION BY TELEPHONE

The undersigned's office is located in the United Kingdom, and hence the Examiner may have difficulty contacting him from the USPTO by telephone. If the Examiner wishes to speak with the undersigned by telephone, he can contact the undersigned by e-mail at martinahay@martin-a-hay.com, or leave a message with Linda McDonald at (317) 433 7140 (Eli Lilly and Company).

CONCLUSION

Applicants believe that the amendments they have made have placed the application in order for allowance.

Favorable consideration of the application is requested.

Respectfully submitted,

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